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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 12/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/970,544

Applicant(s)

CHERVET ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

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1. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17 are unclear as to the scope of the claims in that the claims are replete with references to the liquid chromatography setup recited in the preamble and not a positively recited element of the claims. For example, claim 1 recites a micro switching valve unit and a secondary pump system (which are not even operatively coupled) and nothing more. The "first flow rate" recited relative to the valve unit is dependent upon the chromatographic set up, not the valve unit—any multiport micro valve unit having two positions and any pump unit that can be coupled to that valve unit satisfies the limits of the claim, because any multiport micro valve and pump can be configured to satisfy the functional limitations relative to the unclaimed elements. Similarly, the "wherein..." clause relates to an intended method of use, not a structural limitation. In claim 2, the control unit is positively recited, but is coupled to the post column detector, which is not a positively recited element of the invention. See also claim 13. Claims 3, 5, 6, 8-12 all provide limitations to the setup (not claimed) and method of use which do not clearly further limit the structure of the valve, pump and controller, the only positively recited elements of the claims. If applicant merely intends, e.g., that the controller is capable of outputting a signal which can be input to an NMR or MS (claim 9), or that the valve is capable of passing a first flow rate of 50-400 nl/min (claim 8), then the claims are sufficiently clear. However, in order to meet the

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limitations, the prior art does not have to actually teach a method, e.g., in which a first flow rate is 50-400 nl/min, because such has not been claimed.

In claim 13, line 6, "normal but," is unclear. In claims 15-17, "means for producing" lacks antecedent basis.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 13, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spraul et al.

Spraul teaches a method and apparatus for peak parking between a liquid chromatograph and detectors, such as NMR and/or MS. Control software can take information from the MS detector to make decisions for further action and mode selection (col. 9, lines 23-25). Samples passing through a low dead volume multiport valve unit 38 are passed to the detector(s) at a flow rate slower than the chromatographic speed by a dilution pump 86, shown as a syringe pump (col. 10, lines 46-50, col. 12, lines 40-45). Although the specific examples involve sample loop collection, the device can also be used in stopped flow mode (col. 9, line 52).

Spraul fails to explicitly teach an embodiment using stopped-flow mode.

It would have been obvious to stop flow through the column during peak analysis using the slower flow rate of pump 86 and resume flow after peak analysis in order to operate in stopped-flow mode as taught by Spraul. In that Spraul teaches devices and methods substantially as disclosed, it is the examiner's position that the claimed pressure and/or gradient maintenance is inherent. With respect to specified flow parameters, it would have been obvious to optimize the result effective-variable of flow rate in order to optimize separation and/or detection quality and/or time.

6. Claims 1-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spraul as applied to claims 13, 16-20 above, and further in view of EP 0495255.

Spraul fails to teach a micro valve, micro pump or flow splitter.

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EP teaches a miniature chromatographic system including a flow splitter to provide reduced flow rates to a micro column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a micro valve and micro pump in the invention of Spraul in order to perform small scale separation and analysis as taught by EP. Note that applicant admits that the instant micro valve is commercially available. With respect to claims 10-11, note first that the gradient producer and flow splitter are not positively recited. Nevertheless, it would have been obvious to provide a flow splitter and gradient former in order to provide gradient elution to the modified column of Spraul in order to provide accurate chromatographic flow to a small scale column as taught by EP.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

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Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

jml  
December 3, 2002